STATISTICAL ANALYSIS PLAN

Protocol Title:	**A Phase 1b, Open-label Study of the Safety and Pharmacokinetics of EDG-5506 in Adults with Becker Muscular Dystrophy**
Protocol Number:	EDG-5506-002
Protocol Version/Date:	V6, Amendment 5 / 08MAR2023
Phase:	Ib
Investigational Product:	EDG-5506
Regulatory Agency Identifier:	IND148144
Sponsor:	Edgewise Therapeutics 1715 38th Street Boulder, CO 80301 United States of America
SAP Version/Date:	1.0 / 09Feb2024

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SIGNATURE PAGE

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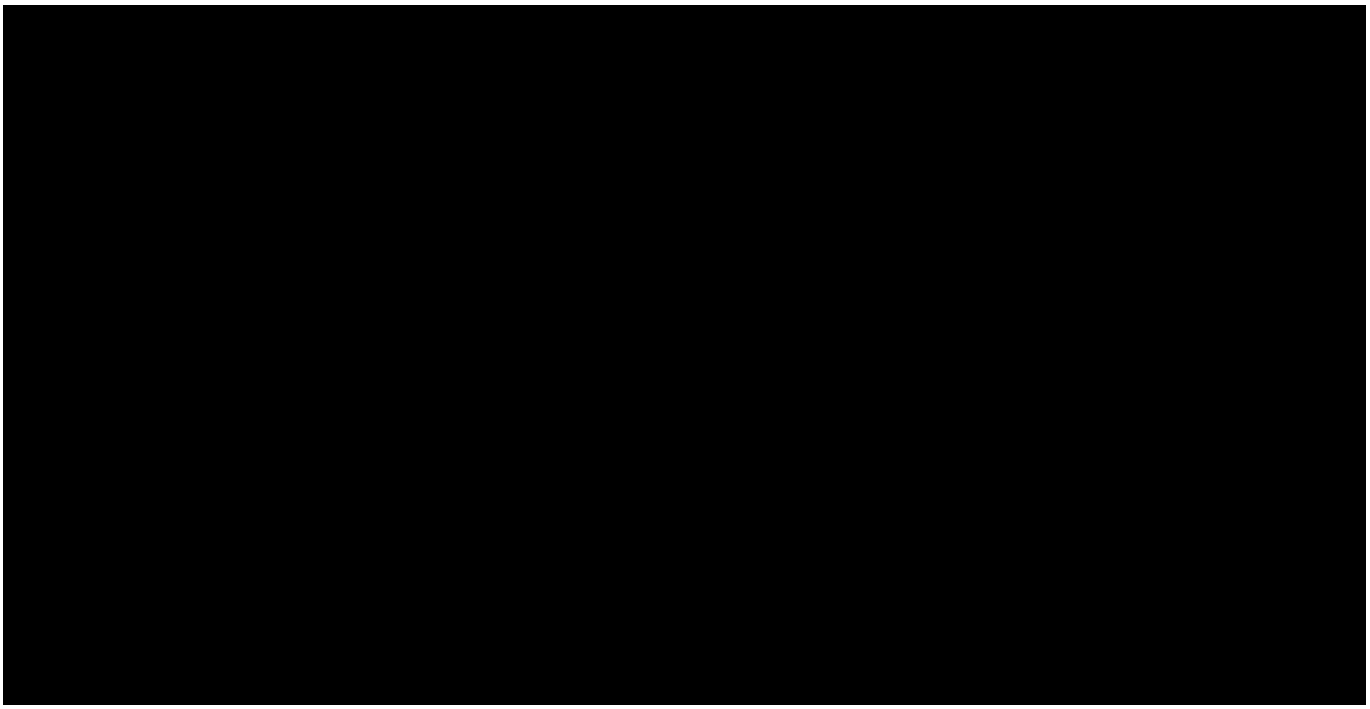
We, the undersigned, have reviewed and approved this Statistical Analysis Plan:

Signature **Date**



VERSION HISTORY

Version	Version Date	Description
0.1	07Mar2023	First draft version.
1.0	09Feb2024	Final version.

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LIST OF ABBREVIATIONS

Abbreviation	Definition
AE	Adverse event
ATC	Anatomical therapeutic chemical
BL	Baseline
BMD	Becker Muscular Dystrophy
CFB	Change-from-baseline
CK	Creatine kinase
CRF	Case report form
CSR	Clinical Study Report
C-SSRS	Columbia Suicide Severity Rating Scale
CTCAE	Common Terminology Criteria for Adverse Events
DMC	Data Monitoring Committee
ECG	Electrocardiogram
FEV_1	Forced Expiratory Volume in one second
FVC	Forced Vital Capacity
LOCF	Last Observation Carried Forward
MedDRA	Medical Dictionary for Regulatory Activities
NCI	National Cancer Institute
NT-proBNP	N-terminal prohormone brain natriuretic peptide
PK	Pharmacokinetics
PKP	Pharmacokinetics population
PT	Preferred Term
RBC	Red blood cell
SAE	Serious adverse event
SAF	Safety population
SAP	Statistical Analysis Plan
SI	International System
SOC	System Organ Class
TEAE	Treatment-emergent adverse event
TFT	Timed Function Test
TLF	Tables, Listings, Figures
WBC	White blood cell
WHO	World Health Organization

1 INTRODUCTION

The purpose of this Statistical Analysis Plan (SAP) is to provide a description of the statistical methods to be implemented for the analysis of data from the study with protocol number EDG-5506-002. This document is based on Protocol Amendment 4 (Protocol Version 5) dated 11October2022. This SAP supersedes the statistical considerations identified in the study protocol; where considerations are substantially different, they will be so identified. The SAP will be finalized prior to database lock. Any deviations from or revisions to the SAP after database lock will be documented in the final Clinical Study Report (CSR).

2 STUDY OVERVIEW

2.1 Rationale and Design

EDG-5506 selectively modulates fast muscle myosin to reduce muscle stress caused by the absence of dystrophin. By protecting fast muscle fibers, EDG-5506 can potentially limit muscle breakdown and disease progression in Becker muscular dystrophy (BMD). This open-label study will evaluate the safety and pharmacokinetics (PK) of EDG-5506 in participants with BMD.

This is an open-label, single-center, Phase 1b study to assess the safety and PK of EDG-5506 in adults with BMD. This study will enroll participants who completed (through Day 42) the first-in-human study, EDG-5506-001. If necessary, additional (treatment-naïve) participants from outside the EDG-5506-001 study may be enrolled to meet the target sample size.

2.2 Study Objectives and Endpoints

Primary Objective	**Primary Endpoints**
• To assess the safety and tolerability of EDG-5506 in adults with BMD	• Incidence, frequency and severity of adverse events (AEs), and serious adverse events (SAEs) in participants treated with EDG-5506
Secondary Objectives	**Secondary Endpoints**
• To assess the change in individual safety parameters	• Incidence of treatment-emergent (TE) abnormal laboratory test results (clinical chemistry, hematology, coagulation and urinalysis) • Change from baseline (CFB) in: o Safety laboratory parameters o Vital signs o Physical and neurological examinations o Cardiac function, as assessed by electrocardiogram (ECG) parameters o Cardiac function, as assessed by an echocardiogram o Pulmonary function, as assessed

	by forced expiratory volume in one second (FEV_1) and forced vital capacity (FVC) ○ Columbia Suicide Severity Rating Scale (C-SSRS)
• To assess the PK profile of EDG-5506 in adults with BMD	• PK concentration levels of EDG-5506
Tertiary/Exploratory Objectives	**Tertiary/Exploratory Endpoints**
• To investigate the effects of EDG-5506 on biomarkers of muscle fiber damage in adults with BMD	• CFB in biomarker measures as assessed by: ○ Serum creatine kinase (CK) ○ Serum cardiac troponin I ○ Serum myoglobin ○ Serum cardiac troponin T ○ Serum N-terminal prohormone brain natriuretic peptide (NT-proBNP) ○ Plasma troponin I tissue-specific isoforms (fast-skeletal, slow-skeletal) ○ Plasma Somascan® proteomics
• To assess the effects of EDG-5506 on functional measures in adults with BMD	• CFB in functional assessments, as measured by: ○ NSAA ○ NSAD ○ 4-stair climb ○ 100-meter timed test ○ Muscle strength testing
• To assess the effects of EDG-5506 on self-reported outcomes in adults with BMD	• CFB in activity limitations and other self-reported outcomes as assessed by: ○ PROMIS-57 ○ ACTIVLIM

2.3 Randomization and Blinding

Not applicable. This is an open-label and non-randomized study.

2.4 Study Drug Administration

EDG-5506 Administration

All participants will receive EDG-5506. EDG-5506 will be administered at a dose of 10 mg orally until Visit 8, followed by a dose of 15 mg until Visit 13, a dose of 20 mg until Visit 21, followed by a dose of 10 mg until Visit 27.

EDG-5506 will be provided as a 2.5-mg or 10-mg tablet and should be taken at night, prior to bedtime, with or without food. Time of dose will be recorded in the participant diary through the Month 12 visit. Treatment-experienced participants will take the first dose of EDG-5506 at the study site in the morning of Day 1. Participants will continue dosing at home, starting in the evening on Day 2.

Treatment-naïve participants will take the first dose of EDG-5506 at the study site in the morning of Day 1 and return to the site on Day 2 before taking the second dose. Participants will remain at the site on Day 2 to be observed for a minimum of two hours post dose. Participants will continue dosing at home, starting in the evening on Day 3, after travel home from the site has been completed.

2.5 Sample Size Determination

Sample size has been set empirically based on the number of participants who completed (through Day 42) the first-in-human study, EDG-5506-001. If necessary, additional (treatment-naïve) participants from outside the EDG-5506-001 study may be enrolled to meet the target sample size of approximately eight (8) evaluable participants. This will provide reasonable estimates of PK measures and important safety and tolerability measures for this early-stage clinical development.

An evaluable participant is defined as a participant who completes the open-label treatment period without significant protocol deviations.

No formal statistical hypothesis testing is planned.

3 STATISTICAL METHODOLOGY

3.1 General Considerations and Key Definitions

3.1.1 Study Enrollment

Study enrollment occurs when a patient is confirmed to be eligible for the study and commences EDG-5506 treatment.

3.1.2 Analysis Day

Analysis day will be calculated from the date of first dose of EDG-5506. The day of the first dose of study drug will be Day 1, and the day immediately before Day 1 will be Day -1. There will be no Day 0.

3.1.3 Definition of Baseline (BL)

For data collected pre-dose and post-dose, Baseline (BL) is defined as the last non-missing measurement prior to the date of first dose of EDG-5506. For data collected at other “off-treatment” times (i.e., screening, admission [Day -1], and follow-up), BL is defined as the last non-missing measurement prior to dosing on Day 1. For ACTIVLIM and PROMIS57 assessments with no available measurement prior to first dose, if the first available measurement occurs on the date of first dose, then that measurement will be utilized as the BL value.

3.1.4 Change-from-Baseline (CFB)

The CFB will be calculated by subtracting the BL values from the individual post-dose values. If the BL value is missing, the missed measurement will be replaced with the last previously-populated value from the patient's visits, including unscheduled visits, in a last-observation-carried-forward (LOCF) approach. Missing post-BL values will not be replaced. That is, the LOCF approach will only be utilized in replacing BL values.

3.1.5 Summary Statistics

Categorical data will generally be summarized with counts and percentages of patients. The denominator used for the percentage calculation will be clearly defined. Continuous data will generally be summarized with descriptive statistics including n (number of non-missing values), mean, median, standard deviation, minimum, and maximum.

3.1.6 Hypothesis Testing

No formal hypothesis testing is planned.

3.1.7 Handling of Dropouts and Missing Data

Missing data will not be imputed unless otherwise specified. Only observed data will be used in the summaries and analyses. If a patient is lost to follow-up, then the last available measurement will be used.

Missing/Partial Dates:

- In cases of incomplete dates for AEs and concomitant medications, the missing component(s) will be assumed as the most conservative value possible. No imputation of start/end dates or times will be performed.
    - If a medication date is missing or partially missing and it cannot be determined whether it was taken prior or concomitantly, it will be considered a concomitant medication.
    - AEs with incomplete start date and times will be attributed to the treatment according to the following algorithm:
        1. Only the day is reported: The event will be considered treatment emergent unless the end date is present and indicates that the event ended prior to the first dose date.
        2. Only the start year or the day and start year is reported: If the year is after or the same as the year of the first dose date, then the event will be considered treatment emergent unless the end date is present and indicates that the event ended prior to the first dose date.
        3. Only the start month and year are reported: If the month/year is after or the same as the month/year of the first dose date, then the event will be considered treatment-emergent unless the end date is present and indicates that the event ended prior to the first dose date.
        4. Only the time is missing: If the time is missing, but the start date otherwise matches the date of first dose, then the event will be considered treatment-

emergent unless the end date and time are present and indicate that the event ended prior to the first dose date and time.

For treatment-emergent adverse events (TEAEs), time since first dose will be calculated as the difference between the event start date and the first date of dosing plus one and expressed in days. Time since first dose will not be calculated if the start date is partial.

Duration will be calculated for AEs that resolve as the difference between the resolution date and onset date and will be expressed in days, hours and minutes. If either time is missing, duration will be calculated as the difference between the resolution date and onset date plus one and expressed in days. Time since dose and duration will only be calculated when both dates are complete.

3.1.8 Treatment-Emergent Adverse Event (TEAE)

A TEAE is defined as an AE that emerges after the first dose of EDG-5506, having been absent at pretreatment (BL) or:

- Reemerges during treatment, having been present at pretreatment (BL) but stopped before treatment, or
- Worsens in severity during treatment relative to the pretreatment state when the AE is continuous.

Treatment-emergence will be determined by comparing the start date and time of the AE with the actual date and time of first dose of EDG-5506. If the onset date of an AE is missing and the AE resolution date is either after the initial EDG-5506 dose date or is missing, then the AE will be considered treatment emergent. If the onset time of an AE is missing and the start date of the AE is on or before the EDG-5506 dose date, then the AE will be considered treatment emergent.

3.2 Analysis Populations

3.2.1 Safety Population (SAF)

The safety population (SAF) includes all participants who received at least one dose of EDG-5506. All safety analyses will be based on the SAF. The SAF will be used for all participant disposition, demographics, safety measures and functional/clinical assessments.

3.2.2 PK-Evaluable Population (PKP)

The PK-evaluable population (PKP) includes all participants who received at least one dose of EDG-5506 and have a sufficient PK profile to derive at least one PK parameter. The PKP will be used for all summaries of PK and biomarker data.

3.3 Subject Data and Study Conduct

3.3.1 Patient Disposition and Withdrawals

The following patient disposition categories will be summarized via counts and percentages for all enrolled patients:

- Patients who were enrolled
- Patients who were treated with at least one dose of EDG-5506

- Patients who received all protocol-specified doses of EDG-5506
- Patients who discontinued treatment of EDG-5506
- Patients who completed the study
- Patients who discontinued the study
- Patients with interruption of study drug
- Treatment status (experienced vs. naïve).

Based on availability, patients may roll over to the open-label EDG-5506-203 protocol at a visit prior to Month 24. These patients will be considered as completing EDG-5506-002 and their last study visit in EDG-5506-002 will serve as the final data point. Patients in the SAF who discontinued study drug will be summarized by reason for discontinuation (all reasons) via count and percentage. Patients in the SAF who discontinued from the study will be summarized by reason for discontinuation (all reasons) as recorded on the Case Report Form (CRF) via count and percentage.

3.3.2 Demographic and Baseline (BL) Characteristics

The following demographic and BL characteristics will be summarized:

- Age (years)
- Sex
- Race
- Ethnicity
- Height (cm)
- Weight (kg).

Demographic and BL disease characteristics will be summarized with descriptive statistics or counts and percentages, based on the number of participants in the SAF.

3.3.3 Medical History

Medical history will be coded to system organ class and preferred term using the Medical Dictionary for Regulatory Activities (MedDRA) version 24.1 or higher. Counts and percentages of patients with medical history by system organ class and preferred term will be summarized. The table and listing will be sorted alphabetically by System Organ Class (SOC) and Preferred Term (PT). Medical history will be listed by patient. The listing will also display the verbatim text from the study investigators.

3.3.4 Concomitant Medications

Prior and concomitant medications/therapies will be coded to anatomical therapeutic chemical (ATC) class and preferred term using the World Health Organization (WHO) Drug Dictionary version Sept 2021 B3. For summary purposes, medications will be considered prior medications if they stopped prior to the first dose of study drug and concomitant medications if they were taken at any time after the first dose of study drug (i.e., started prior to the first dose of study drug and were ongoing or started after the first dose of study drug). Counts and percentages of patients taking prior and concomitant medications will be summarized by ATC class and preferred term based on the SAF.

3.3.5 Protocol Deviations

All protocol deviations will be presented in data listings.

3.3.6 Study Drug Exposure and Compliance

The extent of exposure to study drug EDG-5506 will be summarized by the following parameters:

- Number of doses administered
- Duration of exposure (in weeks) will be calculated as: [(last dose date of study treatment – first dose date of study treatment) + 1]/7
- Total administered dose
- Total administered dose as a percentage of total planned dose.

  The planned dose is defined as the dose that would be given if no doses were missed and/or no dose reductions were made. The total planned dose is the sum of all planned doses.

- Dose discontinued, delayed or interrupted.

Exposure measures will be summarized based on the SAF.

3.4 Clinical and Functional Assessments

Unless otherwise stated, clinical and functional analyses will be performed on the SAF.

3.4.1 Functional Assessments

The CFB for functional assessments will be summarized at each scheduled time point for the following measures:

- NSAA
- NSAD
- Muscle strength test
- Timed function tests (TFTs)
  - 4-stair climb test summarized as both time and velocity (*unit=1/seconds*)
  - 100-meter timed test summarized as both time and velocity (*unit=meters/second*)
  - 10-meter walk run test summarized as both time and velocity (*unit=meters/second*)
  - Rise from supine summarized as both time and velocity (*unit=1/seconds*).

Note that the four TFT endpoints will be transformed from time to velocity (speed) as indicated by the endpoint's units. If a participant is unable to complete the TFT a velocity of "0" will be imputed.

3.4.2 Clinical Outcomes

The CFB in the following clinical outcomes will be summarized at each scheduled time point:

- Activity limitations (ACTIVLIM)
- Patient-Reported Outcomes Measurement Information System (PROMIS-57).

3.4.3 Subgroups

No subgroup analyses or summaries will be performed.

3.5 Safety Assessment

All safety analyses will be performed using the SAF unless otherwise noted below.

3.5.1 Adverse Events (AEs)

An AE is defined as any untoward medical occurrence in a patient administered a medicinal product. The AE does not necessarily have to have a causal relationship with the study drug. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.

3.5.1.1 General Details

Severity

The severity of an AE will be graded, according to the study protocol definitions of AE severity/intensity, as “mild”, “moderate” or “severe”.

Related

Each AE relationship to the study drug will be classified as either “related” or “not related”.

Each AE verbatim term will be coded in accordance with the MedDRA® dictionary to a SOC and PT within each SOC. Analysis of AEs will then be performed using SOCs and PTs.

3.5.1.2 AE Summaries

A patient who reported multiple AEs that map to a common PT or SOC is counted only once for that PT or SOC at the highest severity reported and at the greatest relationship to study drug. The number and percentage of subjects who experienced at least one AE will be tabulated by SOC and PT with respect to dose level/treatment group for each study part. The same tabulation will also be applied to any SAE, any AE leading to premature discontinuation from the study, TEAEs and treatment-emergent SAEs.

The number and percentage of patients who experienced at least one AE will also be tabulated by SOC and PT within each dose level/treatment group with respect to relationship to study drug (related, not related) and severity (mild, moderate, severe).

Patient listings will also be provided for all AEs, all SAEs, all AEs leading to early discontinuation from the study and all AEs leading to study drug interruptions. Length of interruptions will also be provided.

An overview of AEs will be provided including counts and percentages of patients with the following:

- Any TEAEs (overall and by maximum severity)
- Any study drug-related TEAEs
- Any serious AEs (SAEs)
- Any TEAEs leading to discontinuation of study drug
- Any TEAEs leading to discontinuation of study

- Any AEs leading to death.

Separate tables including counts and percentages of patients will also be presented by system organ class and preferred term for each of the categories in the overview.

If an AE has incomplete start or stop dates, dates will be imputed to determine whether the AE was treatment-emergent. Details on the imputation for incomplete dates will be provided in the final SAP to correspond to CRF design and instructions.

Patient listings of all AEs will be presented, as well as listings specifically for SAEs and TEAEs leading to discontinuation of study drug.

3.5.2 Physical and Neurological Examinations

All physical and neurological examination results will be presented in data listings.

3.5.3 Clinical Laboratory Assessments

Safety laboratory evaluations obtained from the following clinical laboratory tests will be collected:

- Hematology – complete blood count, including: reticulocytes (%), hematocrit, hemoglobin, platelet count, red blood cell (RBC) count, white blood cell (WBC) count, WBC with differential, including percentage and absolute measures for neutrophils, lymphocytes, monocytes, eosinophils and basophils.
- Chemistry – alanine aminotransferase, albumin, alkaline phosphatase, aspartate aminotransferase, bicarbonate, blood urea nitrogen, calcium, chloride, cholesterol, creatine phosphokinase, creatinine, cystatin C, gamma-glutamyl transferase, glucose, glutamate dehydrogenase, lactate dehydrogenase, magnesium phosphorus, potassium, sodium, total bilirubin, direct bilirubin, indirect bilirubin, total protein, triglycerides and uric acid.
- Coagulation – prothrombin time (partial) and thromboplastin time.
- Urinalysis – bilirubin, color and appearance, glucose, ketones, leukocytes, RBC, WBC, nitrite, occult blood, pH, protein, specific gravity and urobilinogen.

Results of all evaluations (normal, abnormal clinically significant, abnormal not clinically significant, not done) from each laboratory test will be tabulated by study visit. Descriptive statistics will be provided using the International System of Units (SI units), including absolute and percentage CFB. Both scheduled and unscheduled post-BL values will be included. Unscheduled visits will be summarized as one summary assessment at the end of all scheduled study visit summaries.

A listing of all laboratory evaluations and abnormal clinically significant laboratory evaluations will also be provided. Laboratory values outside the normal ranges will be flagged in the data listings.

3.5.4 Vital Signs

Vital signs include systolic blood pressure (mm Hg), diastolic blood pressure (mm Hg), pulse rate (bpm), respiratory rate (bpm), temperature (°C), height (cm), weight (kg), arm span (cm) and ulna length (cm) (arm spans and ulna length only if subject is unable to stand for a standing

height measurement). . Summary statistics for vital sign values and the CFB will be presented at each scheduled visit. A listing of vital signs will also be provided.

3.5.5 Electrocardiograms (ECGs)

For standard supine resting 12-lead ECG parameters, descriptive statistics will be provided for the ECG measurements at BL (PR, QRS, QT, QTcB, QTcF, RR) and CFB for the minimum post-BL value, maximum post-BL value, and last post-BL value. Both scheduled and unscheduled post-BL values will be considered for the summaries. Outlying QTcF and QTcB intervals will be determined using the criteria outlined below.

Absolute QTc interval prolongation categories include:

- QTc interval >450 msec,
- QTc interval >480 msec, or
- Any QTc interval >500 msec.

CFB measurement in QTc interval categories include:

- QTc interval increase >30 msec, or
- QTc interval increase >60 msec.

Number and percentage of subjects for each category above will be provided.

For interpretation of clinical significance (abnormal, indeterminate, normal, not evaluable/unknown), a frequency table will be presented at each post-dose assessment and for the worst value between post-dose assessments.

Summary statistics for electrocardiogram values and the CFB will be presented by treatment group at each scheduled visit. ECG results will be listed at each assessment.

3.5.6 Dual-energy X-ray Absorptiometry (DXA) Assessment

Summary statistics for DXA values and the CFB will be presented by treatment group at each scheduled visit.

3.5.7 Spirometry

All spirometry results will be presented in data listings.

3.5.8 Other Safety Assessments

All other safety assessments (echocardiograms, oculofacial assessments and C-SSRS will be presented in patient-level data listings.

3.6 Pharmacokinetics (PK)

Samples will be collected for measurement concentrations of EDG-5506 and its metabolites. Summary statistics of concentration values and associated listings will be provided.

3.7 Biomarkers

Biomarker samples will be used for analysis of fast and slow skeletal troponin I, cardiac troponin I, cardiac troponin T, NT-proBNP, myoglobin and CK. Summary statistics of these values and associated listings will be provided.

3.8 Interim Analysis

No formal interim analysis is planned.

4 DATA MONITORING COMMITTEE (DMC)

An independent Data Monitoring Committee (DMC) will be established to enhance the safety of trial participants by providing an independent review of the study data. Details related to the DMC responsibilities, authorities and procedures will be documented in the DMC Charter.

5 CHANGES FROM PROTOCOL-SPECIFIED STATISTICAL ANALYSES

This SAP does not deviate from the statistical analysis described in Amendment 4, Version 5 of the study protocol. Any deviations from the protocol or SAP will be described in the CSR.

6 PROGRAMMING SPECIFICATIONS

Analyses will be performed using SAS® version 9.4 or higher. All available data will be presented in patient-level data listings which will be sorted by patient identification number and visit date as applicable. Detailed programming specifications will be provided in a separate document. TLF shells and specifications will be provided separately as stand-alone documents.

APPENDIX A: TABLES, LISTINGS AND FIGURES

Table Number	Title	Population
	Subject Data and Study Conduct	
14.1.1	Participant Disposition	SAF
14.1.2	Demographics and Baseline Characteristics	SAF
14.1.3	Medical History	SAF
14.1.4	Concomitant Medications	SAF
14.1.5	Participant Exposure and Treatment Compliance	SAF
	Efficacy and Clinical Outcome Assessments	
14.2.1	NSAA	SAF
14.2.2	NSAD	SAF
14.2.3	Four-Stair Climb	SAF
14.2.4	100-meter Timed Test	SAF
14.2.5	10-m Walk/Run Test	SAF
14.2.6	Rise-From-Supine Test	SAF
14.2.7	Muscle Strength Test	SAF
14.2.8	ACTIVLIM	SAF
14.2.9	PROMIS-57	SAF
	Safety Assessments	
14.3.1	Overview of Adverse Events	SAF
14.3.2.1	Adverse Events by SOC and PT	SAF
14.3.2.2	Adverse Events by Maximum Severity, SOC and PT	SAF
14.3.2.3	Study-drug Related Adverse Events by SOC and PT	SAF
14.3.2.4	Treatment-Emergent Adverse Events Leading to Study	SAF

	Drug Discontinuation by SOC and PT	
14.3.2.5	Adverse Events Leading to Death by SOC and PT	SAF
14.3.3	Summary of Vital Signs	SAF
14.3.4.1	Summary of Clinical Laboratory Assessments: Chemistry	SAF
14.3.4.2	Summary of Clinical Laboratory Assessments: Hematology	SAF
14.3.4.3	Summary of Clinical Laboratory Assessments: Coagulation	SAF
14.3.4.4	Summary of Clinical Laboratory Assessments: Urinalysis	SAF
14.3.5	Summary of ECGs	SAF
14.3.6	Summary of DXA Assessments	SAF
	Pharmacokinetics	
14.4.1.1	Summary of Pharmacokinetics (PK) Concentrations	PK
	Biomarkers	
14.4.2.1	Summary of Biomarkers	PK

Listing Number	Title
	Disposition
16.2.1.2	Protocol Deviations
	Participant Demographics and Characteristics
16.2.4.2	Medical History
16.2.4.3	Concomitant Medications
	Exposure
16.2.5	Study Drug Exposure and Compliance
	Adverse Events

16.2.7.1.1	Adverse Events
16.2.7.1.2	Serious Adverse Events
	Other Safety Assessments
16.2.8.1	Vital Signs
16.2.8.2.1	Clinical Laboratory Assessments: Chemistry
16.2.8.2.2	Clinical Laboratory Assessments: Hematology
16.2.8.2.3	Clinical Laboratory Assessments: Coagulation
16.2.8.2.4	Clinical Laboratory Assessments: Urinalysis
16.2.8.3	ECGs
16.2.8.4	DXA
16.2.8.5	Spirometry
16.2.8.6	Physical and Neurological Examination
16.2.8.8	Echocardiogram
	Pharmacokinetics (PK) and Biomarkers
16.2.9.1.1	PK Concentrations
16.2.9.2.1	Biomarkers